K023664

510(K) SUMMARY

FEB 21 2003

Submitter's Name:	David E. Curtin, RAC
Address:	1620 Waukegan Rd. MPGR-A2E
Phone:	(847) 473-6079
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Contact:	David E. Curtin
Date Prepared:	5/14/02
Trade Name:	Syntra™ + Dialyzer
Common Name:	Dialyzer
Classification Name:	High Permeability Hemodialysis System per 21 CFR 876.5860
Equivalent Predicate:	Syntra™ Dialyzer (K002210)
Device Description:	Model 200 Dialyzer
Intended Use:	Hemodialysis with Syntra™ + dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

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Summary of the Technological Characteristics Compared to the Predicate Device:	The general design and material of the Syntra™ + Dialyzer is similar to the Syntra™ Dialyzers cleared under K002210, and do not raise any new types of safety and effectiveness issues, when compared to the predicate product.
Clinical Data:	N/A
Conclusions Drawn	Components of the subject Syntra™ + dialyzer have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests. The validation of the gamma sterilization cycle for the Syntra™ Plus dialyzer is based upon the AAMI/ISO 11137:1994 "Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization". Pyrogen testing of the subject dialyzer meets the requirements of USP 24 <161>, Transfusion and Infusion Assemblies and Similar Medical Devices. Particles are counted per USP XXIII Monograph <788>. This procedure is performed initially for information only and is not a release criteria at this time. Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.
Additional Information Requested by FDA:	None to date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

David E. Curtin, R.A.C.
Associate Director, Regulatory Affairs
Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K023664
Trade/Device Name: Syntra™ + Dialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: February 3, 2003
Received: February 4, 2003

Dear Mr. Curtin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K023664

Device Name: **Syntra™ + Dialyzer**

Indications For Use:

Hemodialysis with Syntra™ + is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023664